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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/863,818	05/23/2001	Daniel M. Gorman	DX01170K	8990

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EXAMINER
JIANG, DONG

ART UNIT	PAPER NUMBER
1646	

DATE MAILED: 10/01/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/863,818	GORMAN, DANIEL M.	
	Examiner	Art Unit	
	Dong Jiang	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 October 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-20* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1 in part (parts a), b), e), and f)), 2, 3 in part, and 6, drawn to a composition of a polypeptide comprising small amino acid segments of a specific amino acid sequence, and a kit thereof, classified in class 530, subclass 300.

II. Claims 1 in part (parts c), d), g), and h)), 2, 3 in part, and 4-6, drawn to a composition of a polypeptide comprising a natural or a mature form of the polypeptide, and a kit thereof, classified in class 530, subclass 350.

III. Claims 7, 8, and 11, drawn to a binding compound comprising an antigen binding site from an antibody, and a kit thereof, classified in class 530, subclass 387.9.

IV. Claims 9 and 10, drawn to a method of producing an antigen:antibody complex, classified in class 435, subclass 7.1.

V. Claims 12 in part, 13, 14, 15 in part, and 16-18, drawn to an isolated nucleic acid, a host cell containing the nucleic acid, and a kit comprising the nucleic acid, encode a full-length or mature form of a polypeptide, classified in class 435, subclass 69.1.

VI. Claims 12 in part, 13, 14, 15 in part, and 16-18, drawn to an isolated nucleic acid comprising small fragment(s) of a nucleic acid, a host cell containing the nucleic acid, and a kit comprising the nucleic acid, classified in class 435, subclass 69.1.

VII. Claim 15 in part, drawn to a kit comprising the nucleic acid and a polypeptide, classified in class 436, subclass 808.

VIII. Claims 19 and 20, drawn to a method of modulating physiology or development of a cell with an *agonist* of said polypeptide, classification depending upon the chemical entity of the agonist.

IX. Claims 19 and 20, drawn to a method of modulating physiology or development of a cell with an *antagonist* of said polypeptide, classification depending upon the chemical entity of the antagonist.

The inventions are distinct, each from the other because:

Although both inventions I and II are drawn to a polypeptide, they are distinct for the following reasons: invention II is directed to a full length or mature form of a polypeptide, whereas invention I is drawn to a polypeptide comprising the small fragment thereof. Due to the use of 'comprising' language, it cannot even be said that the search for the full length polypeptide (SEQ ID NO:10, 12 or 14) would reveal art pertaining to, for instance a polypeptide *comprising* at least two distinct non-overlapping segments of at least 5 amino acids identical to segments of SEQ ID NO:10 (claim 1, part b)), as the latter could be found embedded in a completely different protein. As so, non-coextensive searches are required.

The polypeptide of Inventions I and II is related to the antibody of Invention III by virtue of being the cognate antigen, necessary for the production of the antibodies. Although the protein and antibody are related due to the necessary stearic complementarity of the two, they are distinct inventions because they are physically and functionally distinct chemical entities, and because the protein can be used another and materially different process from the use for production of the antibody, such as in a pharmaceutical composition in its own right, or in assays for the identification of agonists or antagonists of the protein.

Inventions I and II are related to Invention IV as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product as claimed may be used as a pharmaceutical composition in its own right, or in assays for the identification of agonists or antagonists of the protein.

The polypeptide of Inventions I and II is related to the nucleic acids of Inventions V and VI by virtue of being encoded the same. The nucleic acid molecule has utility for the recombinant production of the protein in a host cell. Although the nucleic acid molecules and proteins are related since the nucleic acid encodes the specifically claimed protein, they are distinct inventions because they are physically and functionally distinct chemical entities, and the protein product can be made by another and materially different process, such as by synthetic

peptide synthesis or purification from the natural source. Further, the nucleic acid may be used for processes other than the production of the protein, such as nucleic acid hybridization assay.

Inventions I and II are distinct from Invention VII because Invention VII comprises additional element, the nucleic acid, thus separate searches are required.

Inventions I and II are distinct from and unrelated to Inventions VIII and IX, wherein the polypeptide of Inventions I and II is neither made by nor used in the methods of Inventions VIII and IX, and wherein each does not require the other.

Invention III is related to Invention IV as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product as claimed may be used as a pharmaceutical composition in its own right.

The antibody of Invention III is distinct from and unrelated to the nucleic acid of Inventions V-VII because they are physically and functionally distinct chemical entities which share neither structure nor function. Also, neither is required for the manufacture of the other.

Invention III is distinct from and unrelated to Inventions VIII and IX, wherein the antibody of Invention III is neither made by nor used in the methods of Inventions VIII and IX, and wherein each does not require the other.

The complex of Invention IV is distinct from the nucleic acid of Inventions V-VII because they are physically and functionally distinct chemical entities which share neither structure nor function. Also, neither is required for the manufacture of the other.

Invention IV is distinct from and unrelated to Inventions VIII and IX, wherein the complex of Invention IV is neither made by nor used in the methods of Inventions VIII and IX, and wherein each does not require the other.

Although both inventions V and VI are drawn to a nucleic acid, they are distinct for the following reasons: invention V is directed to a nucleic acid encoding a full length or mature form of a polypeptide, whereas invention VI is drawn to a small fragment of the nucleic acid (as a primer for example), or a nucleic acid encoding a polypeptide comprising the small fragment thereof. Due to the use of 'comprising' language, it cannot even be said that the search for the

nucleic acid encoding full length polypeptide (SEQ ID NO:10, 12 or 14) would reveal art pertaining to, for instance, a nucleic acid encoding a polypeptide comprising merely small fragments of said polypeptide, as the latter could be found embedded in a completely different nucleic acid. As so, non-coextensive searches are required.

Inventions V and VI are distinct from Invention VII because Invention VII comprises an additional element, the polypeptide, thus separate searches are required.

Inventions V and VI are distinct from and unrelated to Inventions VIII and IX, wherein the nucleic acid of Invention V is neither made by nor used in the methods of Inventions VIII and IX, and wherein each does not require the other.

Invention VII is distinct from and unrelated to Inventions VIII and IX, wherein the nucleic acid and the polypeptide of Invention V are neither made by nor used in the methods of Inventions VIII and IX, and wherein each does not require the other.

Invention VIII is distinct from Invention IX because different active ingredients are used in the methods, and they are physically and functionally distinct chemical entities, and share neither structure nor function. Thus, separate searches are required.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and/or recognized divergent subject matters, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

2. Furthermore, regardless of which Invention applicants elect above, further **restriction** is required under 35 U.S.C. 121:

A. One specific polypeptide sequence with SEQ ID NO:, i.e., elect one from SEQ ID NO:10, 12, and 14; *and* one specific DCR corresponding to the elected SEQ ID NO, i.e., elect DCRS8 *or* DCRS9.

The inventions are distinct, each from the other because of the following reasons:

Although there are no provisions under the section for "Relationship of Inventions" in M.P.E.P. § 806.05 for inventive groups that are directed to *different* products, restriction is deemed to be proper because these products constitute patentably distinct inventions for the following reasons. Each of SEQ ID NOs is a unique and separately patentable sequence, requiring a unique search of the prior art. Searching all of the sequences in a single patent application would constitute an undue search burden on the examiner and the USPTO's resources because of the non-coextensive nature of these searches.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

In order to be fully responsive, Applicant must elect one from Groups I - IX, one from Group A, even though the requirement is traversed. Applicant is advised that neither I - IX nor A are species election requirements; rather, each of I – IX, and A is a restriction requirement.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Claim Interpretation:

"DCRS8" and "DCRS9" are being interpreted as meaning the full-length or mature form, and excluding a polypeptide comprising fragments of SEQ ID NO:10, 12 or 14 in view of the definition in the specification on page 41, line 6-10. If Applicants disagree with this interpretation, they are required to specify the intended meanings of the terms and point out consequent changes to the restriction grouping set forth above.

Advisory Information

Any inquiry concerning this communication should be directed to Dong Jiang whose telephone number is 703-305-1345. The examiner can normally be reached on Monday - Friday from 9:30 AM to 7:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, can be reached on (703) 308-6564. The fax phone number for the organization where this application or proceeding is assigned is 703-308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

CLAIRE KAUFMAN
PATENT EXAMINER

Dong Jiang, Ph.D.
Patent Examiner
AU1646
9/12/02